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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,809	08/01/2003	Chee-Keung Chung	33229-182586	2011

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,809	CHUNG ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0803.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase "sporoderm-broken germination activated *Ganoderma Lucidum* spores (GASP)" - i.e., what does the phrase "germination activated" therein actually mean with respect to the claimed spores (e.g., in what way are they activated - are they activated in some way via germination so as to produce enhanced amounts of active byproducts; activated during germination via softening/breaking the spore wall so as to release internal active agents, activated to grow faster during and/or after germination, activated via extraction of the active agents therefrom, or some other activation?). Accordingly this phrase, in and of itself, does not adequately delineate its metes and bounds. It is apparent that the sporoderm-broken germination activated spores are clearly an essential limitation of the instantly disclosed invention (see, e.g., pages 12-14 of the instant specification) in terms of providing the difficult-to-achieve therapeutic effect instantly claimed/disclosed. Accordingly, it is strongly suggested that this phrase be adequately expanded upon so as to clearly define this essential limitation (see MPEP 2172.01) with regard to the overall preparatory process set forth on pages 12-14 of the instant specification - e.g., as a product-by-process (within the claimed method)

since product-by-process claims are intended to define products which are otherwise difficult to define and/or distinguish from the prior art (e.g., --, whereby the sporoderm-broken germination activated *Ganoderma lucidum* spores are prepared by ...--) using the claim language recited within the preparative methods of Applicants' previously allowed related applications as a guide (see, e.g., US Patent Nos: 6,468,542 and 6,316,002). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the China Daily Business Weekly bulletin entitled "Paralysis Drug" (CIN Abstract, 1997), in view of Wang (CN 1111529 - DWPI Abstract), Tan et al. (CN 1101860 - DWPI Abstract), Dorland's Medical Dictionary (27th ed., 1988), and Cheung et al. (FERS Letters, 2000).

A method of treating a spinal cord injury via administering an effective amount of sporoderm-broken germination activated Ganoderma spores to a mammal having spinal cord injury is claimed.

The China Daily Business Weekly bulletin entitled "Paralysis Drug" beneficially teaches a medicine for treating paralysis which is composed of glossy ganoderma as the active ingredient therein - see CIN Abstract. Please note that glossy ganoderma preparations are well recognized in the Chinese medicinal art as being typically composed of powdered ganoderma spores and thus reasonably reads upon "sporoderm-broken germination activated Ganoderma spores", as best understood (as evidence - see, e.g., the cited DWPI Abstracts of Wang and Tan et al. concerning conventional Chinese medicinal glossy ganoderma compositions).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a subject having paralysis with the glossy ganoderma medicinal preparation beneficially disclosed by the cited 1997 China Daily Business Weekly bulletin, including a subject suffering from paralysis caused by spinal cord injury (such as a conventional powdered glossy ganoderma medicinal preparation, as discussed above) because the teachings of this reference are broadly applicable to treating any type of paralysis including paralysis and, thus, would not preclude its use in treating commonly encountered spinal cord injuries such as those brought about by trauma (a leading cause of paralysis) and/or those involving one of various disease states (including those instantly disclosed - e.g.., spina bifida, Friedreich's Ataxia, polio) and, further, because paralysis is well known in the medical art to encompass paralytic states brought about by spinal cord injuries (see, e.g., the various forms/types of paralyses encompassed by the definition of "paralysis" in Dorland's Medical Dictionary).

Accordingly, it would have been obvious to one of ordinary skill in the art to treat a particular type of paralysis including those instantly claimed/disclosed via administering an effective amount of the glossy ganoderma preparation beneficially taught by the cited 1997 China Daily Business Weekly bulletin. The *in vivo* functional effects instantly claimed with respect to improving neuron survival and/or promoting axon regeneration (particularly in light of the evidence provided by Cheung et al. regarding the *in vitro* neuroprotective activity of ganoderma extract preparations - see entire article including Abstract and Discussion) would be intrinsic upon administration/ingestion of the medicinal glossy ganoderma preparation beneficially taught by the cited 1997 China Daily Business Weekly bulletin. The adjustment of particular conventional working conditions (e.g., treating a particular type of spinal cord injury and/or determining an appropriate result-effective dosage range thereof, etc) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/752,685. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method of treating a subject suffering from spinal cord injury via administering an effective amount of sporoderm-broken germination activated Ganoderma spores (GASP) thereto. Further, please note that the *in vivo* functional effects instantly claimed (e.g., improving neuron survival and/or axon regeneration) vs. the *in vivo* functional effects claimed in Application '685 (e.g., promoting neural stem cell proliferation and/or differentiation) would be intrinsic upon such administration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1654